IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

DULUTH PHARMACY, LLC
3890 Pleasant Hill Road, Suite 101
Duluth, Georgia 30096

Plaintiff,

v.

PAMELA J. BONDI, in her official capacity as the Attorney General of the United States, 950 Pennsylvania Avenue, NW, Washington, D.C., 20530

U.S. DEPARTMENT OF JUSTICE, 950 Pennsylvania Avenue, NW, Washington, D.C., 20530

DEREK S. MALTZ, in his official capacity as Acting Administrator of the Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152

DRUG ENFORCEMENT ADMINISTRATION, 8701 Morrissette Drive, Springfield, Virginia 22152,

Defendants.

COMPLAINT AND PRAYER FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Duluth Pharmacy, LLC ("Duluth Pharmacy"), for its complaint against Defendants the Honorable Pamela J. Bondi, in her official capacity as Attorney General of the United States, the U.S. Department of Justice, the Honorable Derek S. Maltz, in his official capacity as Acting Administrator of the Drug Enforcement Administration, and the Drug Enforcement Administration ("DEA"), alleges as follows:

INTRODUCTION

- 1. This is an action under the Administrative Procedure Act, 5 U.S.C. §§ 551–706 ("APA"), challenging an Order to Show Cause and Immediate Suspension of Registration ("Immediate Suspension Order" or "ISO") issued on or about May 1, 2025, and served that same day on Duluth Pharmacy, a licensed Georgia pharmacy and DEA registrant. The ISO immediately suspended Duluth Pharmacy's registration to dispense controlled substances without providing any prior notice or opportunity to be heard.
- 2. The ISO asserts that Duluth Pharmacy's continued registration poses an "imminent danger to the public health or safety" and required Duluth Pharmacy to immediately cease dispensing controlled substances. The Order is based on

allegations that Duluth Pharmacy failed to address "red flags" associated with certain controlled substance prescriptions.

- 3. The Controlled Substances Act ("CSA"), 21 U.S.C. § 824(d), authorizes the DEA to issue an immediate suspension of registration only in exceptional circumstances—where continued registration presents an imminent danger to the public health or safety. In the absence of such a finding, the CSA requires DEA to provide the registrant with notice and an opportunity to be heard before suspending a registration. *Id.* § 824(c).
- 4. The DEA's issuance of the ISO to Duluth Pharmacy violates the APA and the CSA in multiple respects. The DEA has failed to demonstrate that Duluth Pharmacy's continued registration presents the kind of imminent danger that justifies the extraordinary remedy of an immediate suspension. Instead, the DEA issued the ISO based on allegations of regulatory noncompliance and without evidence of actual harm, diversion, or illegitimate prescribing at the time of issuance.
- 5. The ISO has caused, and continues to cause, irreparable harm to Duluth Pharmacy, its patients, and the broader community it serves. Duluth Pharmacy is a trusted provider of care for hundreds of patients, including those with chronic pain, palliative care needs, and complex medical conditions. Without the ability to dispense controlled substances, Duluth Pharmacy's operations are effectively

shuttered, threatening both the continuity of care for vulnerable patients and the viability of the business itself.

6. The Court should issue a preliminary injunction to vacate the ISO, thereby restoring the status quo and allowing Duluth Pharmacy to continue to dispense controlled substances while the administrative appeal process is ongoing.

PARTIES

- 7. Plaintiff Duluth Pharmacy is a Georgia Limited Liability Company located at 3890 Pleasant Hill Road, Suite 101, Duluth, Georgia 30096.
- 8. Defendant the Hon. Pamela Bondi is named in her official capacity as the Attorney General of the United States. Under 21 U.S.C. § 824(d), it is the Attorney General that is given the authority to "suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety." The Attorney General has delegated that authority to the DEA Administrator. *See* 28 C.F.R. § 0.100.
- 9. Defendant U.S. Department of Justice is an executive department of the United States. *See* 5 U.S.C. § 101; 28 U.S.C. § 501. The head of the Department of Justice is the Attorney General. *See* 28 U.S.C. § 503.
- 10. Defendant the Hon. Derek Maltz is named in his official capacity as the Acting Administrator of the DEA. The Attorney General's authority to immediately

suspend a registrant pursuant to 21 U.S.C. § 824(d) has been delegated to her. *See* 28 C.F.R. § 0.100.

11. Defendant DEA is a component of the U.S. Department of Justice. It was created by Executive Order 11,727. *See* 38 Fed. Reg. 18357 (July 10, 1973).

JURISDICTION AND VENUE

- 12. This action arises under the Constitution of the United States, the CSA, and the APA. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331. The Court is authorized to issue the non-monetary relief sought herein pursuant to 5 U.S.C. §§ 702, 705, and 706.
- 13. This Court has jurisdiction to hear this matter and dissolve the ISO under 21 U.S.C. § 824(d)(1).
- 14. Venue is proper in this Court under 28 U.S.C. § 139l(e) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.
 - 15. This Complaint is timely under 28 U.S.C. § 2401(a).

FACTUAL ALLEGATIONS

- 16. Duluth Pharmacy is a retail pharmacy located in Duluth GA and holds a DEA Certificate of Registration which authorizes it to dispense controlled substances in Schedules II through V.
 - 17. Duluth Pharmacy is licensed by the State of Georgia.

- 18. On or about May 1, 2025, the DEA issued an Order to Show Cause and Immediate Suspension of Registration (ISO) against Duluth Pharmacy pursuant to 21 U.S.C. § 824(d), alleging that the continued registration of Duluth Pharmacy constitutes an "imminent danger to the public health or safety."
- 19. The ISO was issued without prior notice or opportunity for Duluth Pharmacy to be heard, and it became effective immediately upon service.
- 20. The DEA alleges that from January 5, 2021, through December 26, 2024, Duluth Pharmacy dispensed prescriptions for controlled substances, including opioids and benzodiazepines, despite the presence of numerous unresolved "red flags" indicative of abuse or diversion.
- 21. The DEA claims that Duluth Pharmacy regularly dispensed dangerous "drug cocktails"—combinations of opioids and benzodiazepines—without documenting or resolving any clinical justification or red flags.
- 22. Specific examples cited in the ISO include repeated dispensing of combinations of alprazolam, hydrocodone-acetaminophen, and oxycodone HCL to Patient P.S., and combinations including clonazepam, hydrocodone-acetaminophen, oxycodone HCL, and dextroamphetamine-amphetamine to Patient K.B.
- 23. The DEA further alleges that Duluth Pharmacy dispensed immediaterelease opioids for extended periods, at high dosages, and in therapeutically duplicative combinations—red flags that were allegedly not addressed or resolved.

- 24. For instance, Patient K.B. allegedly received over 120 prescriptions for short-acting opioids between January 2021 and December 2024; Patient P.S. received over 25 prescriptions for immediate-release opioids during similar timeframes; and Patient S.M. received over 18 such prescriptions without documented resolution of concerns.
- 25. The DEA also alleges that Duluth Pharmacy filled prescriptions for patients who appeared to be engaging in "doctor shopping"—obtaining controlled substances from multiple prescribers—specifically citing Patient C.P. and Patient M.R., each of whom allegedly obtained prescriptions from six different practitioners.
- 26. Another allegation involves the high incidence of "cash payments" for controlled substances, which DEA considers a red flag. DEA states that approximately 59.4% of Duluth Pharmacy's 12,137 controlled substance prescriptions dispensed from January 2021 to December 2024 were paid via "Private Pay" (cash, credit, check, or debit), with examples involving Patients K.B., S.M., and D.J.
- 27. The DEA alleges that in none of the aforementioned cases did Duluth Pharmacy appropriately document or resolve the red flags before dispensing the prescriptions.
- 28. The DEA alleges that as recently as December 26, 2024, Duluth Pharmacy continued to dispense controlled substances without resolving red flags,

thereby presenting an "imminent danger" justifying immediate suspension under 21 U.S.C. § 824(d).

- 29. As a result of the ISO, Duluth Pharmacy was immediately prohibited from dispensing any controlled substances, which has caused and continues to cause irreparable harm to Duluth Pharmacy's business operations, patients, and professional reputation.
- 30. On May 29, 2025, Duluth Pharmacy filed a timely request for administrative hearing with the DEA. **Exhibit A.** That request is pending but, under the terms of the ISO, Duluth Pharmacy is unable to dispense controlled substances while it waits its turn for an administrative hearing.

COUNT I (Exceeds Statutory Authority – 5 U.S.C. § 706(2)(C))

- 31. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
 - 32. The ISO is agency action reviewable under 21 U.S.C. § 824(d).
 - 33. Duluth Pharmacy is adversely affected and aggrieved by the ISO.
- 34. Defendants lacked statutory authority to issue the ISO, without prior notice or an opportunity to be heard, because they failed to establish that the Pharmacy's continued registration posed an imminent danger to public health or safety, as required by 21 U.S.C. § 824(d).

35. As a result, the ISO is in excess of statutory authority and limitations, in violation of 5 U.S.C. § 706(2)(C).

COUNT II

(Violation of Due Process – 5 U.S.C. § 706(2)(B))

- 36. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
- 37. The ISO deprived Duluth Pharmacy of property and liberty interests without prior notice or a meaningful opportunity to be heard, in violation of the Fifth Amendment to the U.S. Constitution.
- 38. Duluth Pharmacy was not afforded procedural safeguards commensurate with the severity of the deprivation, nor was there any showing that immediate suspension without notice was necessary.
- 39. The ISO is therefore contrary to constitutional right and in violation of 5 U.S.C. § 706(2)(B).

COUNT III

(Arbitrary and Capricious Agency Action – 5 U.S.C. § 706(2)(A))

- 40. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
- 41. The DEA's decision to issue the ISO was arbitrary, capricious, and not the product of reasoned decision-making.

- 42. Defendants failed to consider relevant mitigating factors, including the Pharmacy's patient population, compliance practices, and absence of actual diversion.
- 43. Defendants failed to evaluate less restrictive alternatives, assess the actual public health impact of the ISO, or justify the necessity of immediate suspension.
- 44. As a result, the ISO is arbitrary, capricious, and not in accordance with law, in violation of 5 U.S.C. § 706(2)(A).

<u>COUNT IV</u> (Inadequate Findings – 5 U.S.C. § 706(2)(D))

- 45. Plaintiff incorporates by reference the allegations in the preceding paragraphs.
- 46. Under 21 C.F.R. § 1301.36(e), an order of immediate suspension must include a statement of the DEA Administrator's findings regarding imminent danger to public health or safety.
- 47. The ISO fails to include adequate findings demonstrating how continued registration would result in such imminent danger.
- 48. Accordingly, the ISO was issued without observance of required procedures, in violation of 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Duluth Pharmacy respectfully requests that this Court enter judgment in its favor and grant the following relief:

- 1. Declare that the Immediate Suspension Order (ISO) issued by the Drug Enforcement Administration on May 1, 2025, is unlawful;
- 2. Vacate and set aside the Immediate Suspension Order (ISO);
- 3. Issue a preliminary injunction enjoining Defendants from enforcing the Immediate Suspension Order (ISO) and restoring Plaintiff's DEA registration during the pendency of the administrative appeal;
- 4. Award Duluth Pharmacy its costs and reasonable attorneys' fees, as appropriate under the Equal Access to Justice Act or other applicable law; and
- 5. Grant such other and further relief as this Court deems just and proper.

[signatures on following page]

This 4th day of June, 2025.

CHILIVIS GRUBMAN, LLP

/s/ Scott R. Grubman

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Counsel for Duluth Pharmacy, LLC

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Motion has been prepared with one of the font and point selections approved by the Court in Local Rule 5.1(C), specifically, Times New Roman, 14 point.

This 5th day of June, 2025.

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CERTIFICATE OF SERVICE

I hereby certify that I served the foregoing Complaint and Prayer for Declaratory and Injunctive Relief to Defendants via Statutory Electronic Service to the following:

The Hon. Pamela J. Bondi Attorney General of the United States U.S. Department of Justice 950 Pennsylvania Avenue, NW Washington, D.C., 20530 The Hon. Derek S. Maltz
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[signatures on following page]

This 5th day of June 2025.

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